CZECH TECHNICAL UNIVERSITY

IN PRAGUE

DOCTORAL THESIS STATEMENT

Czech Technical University in Prague
Faculty of Electrical Engineering
Department of Cybernetics

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Multi-Layer Data Model

Ph.D. Programme: Electrical Engineering and Information Technology
Branch of study: Artificial Intelligence and Biocybernetics

Doctoral thesis statement for obtaining the academic title of “Doctor”, abbreviated to “Ph.D.”

Prague, July, 2012

The doctoral thesis was produced in full-time manner Ph.D. study at the department of cybernetics of the Faculty of Electrical Engineering of the CTU in Prague

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The doctoral thesis statement was distributed on ………….: The defence of the doctoral thesis will be held on …………. at …..……..... a.m./p.m. before the Board for the Defence of the Doctoral Thesis in the branch of study Artificial Intelligence and Biocybernetics in the meeting room No. ………………… of the Faculty of Electrical Engineering of the CTU in Prague.

Those interested may get acquainted with the doctoral thesis concerned at the Dean Office of the Faculty of Electrical Engineering of the CTU in Prague, at the Department for Science and Research, Technická 2, Praha 6.

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1. Current situation of the Studied Problems

Standards are the basis of interoperability between different implementations of Electronic Heath Record. Standardizations should work as bases of architecture that defines method of communication, information exchange and using of data representation, code books and vocabularies. The very important standards (in our opinion) for the exchange of information from medical records are HL7 and HL7 Clinical Document Architecture [1], [2], [3], [4], [5], ENV 13606 (EN 13606 Association), openEHR [6] and DICOM [7], code books and vocabularies Classification of Diseases version 10 (ICD-10) [8] defined by the World Health Organization (WHO), the Systematized Nomenclature of Medicine (SNOMED) [9] and Laboratory Coding System Logical Observation Identifiers Names and Codes (LOINC) [10] and the organizations Continua Alliance (www.continuaalliancce.org) and IHE (http://www.ihe.net/).

Mentioned standards are related to electronic health record (EHR) [11], [12] and EHR is main part of Hospital Information System (HIS) from clinical and healthcare point of view. The EHR is individual patient´s medical record stored in digital format. The EHR can contain several types of patient data, such as the patient´s demographic information, clinical data such as vital signs, medical history, immunizations, laboratory and radiology data, problems and progress notes, accounting and billing records and even legal documents such as living wills and health powers of attorney [12].

Heterogeneous data are defined as data originating from several different source stored usually in different formats. In evidence based medicine, the decision making process nearly always involves dealing with heterogeneous data. In the knowledge and data engineering area the heterogeneous data are often represented by data model, which is interchangeable and suggestible and represents information of each source and makes it possible to combine such information. Representation used for integration of heterogeneous data needs to be competent in data description, schemes and contexts. For the integration purpose different approaches had been used such as object oriented models [13], ontology [14], [15], statistical model [16] or mediated data model [17]. In [14] there is a survey of generally recognized the main heterogeneity integration conflict categories – syntactic, structural and semantic heterogeneity. Approach to semantic heterogeneity is very important for interoperability limitation. The ontology approach offers solution of this limitation [14]. The role of ontologies, metadata and context in information systems semantic heterogeneity is introduced in [18]. Overview of main ontology architectures (single ontology approaches, multiple ontologies, hybrid approaches) and ontology representations can be found in [15]. Data fusion is one of the most important parts of heterogeneous data processing. Data fusion is concerned with combining information from knowledge sources such as sensors to provide a greater understanding of a given situation. Medical diagnostic is based on assembling in formations from various sources – person and family anamneses, basic patient data (age, sex, height, weight, etc), signals measurement (ECG, blood pressure, respiration recording) and their analysis, information form imaging systems (ultrasound, CT, MRI) or results of laboratory analysis - with final diagnosis if available. Often only one source is used for automatic classification. In paper [19] is described the fusion of ECG, blood pressure, saturated oxy content and respiratory data for improving of clinical diagnosis in critical care unit. Many parameters are derived from original record of physiologic parameters (i.g. heart rate, respiratory rate, systolic, mean and diastolic pressure) and these parameters are used as features to data fusion. Paper [20] deals with concept of learning rules from multisource data from monitoring devices in Cardiac Intensive Care Units. Multi-class Inductive Logic Programming is used to learn the rules. In the area of electrophysiology, e.g. in [21], using body surface potential mapping (BSPM) and MRI-based model for solving of inverse task [22] is used. But in those two cases relation between sources is a priory known. The major points uniqueness of medical data are given in four heading - heterogeneity of medical date, ethical, legal and social issues, statistical philosophy and special status of medicine [23]. Overview of used technologies for data mining process model in [24] is introduced and examples of medical data mining cases with various approaches can be found in [25], [26], [27], [28]. Overview of data mining task, data, models and results visualization methods are described in [29].

2. Aims of the Doctoral Thesis

The motivation of this thesis is to find the design and use of appropriate approaches to interoperability in medicine both for the purpose of communication and for knowledge representation, and not only for data, but also for their relationships and the treatment processes, for both categorical data and signals. Integration of the signal in the data model has been never solved in conjunction with draft of semantic description of signals (their behavior), and integration with other inputs of common information systems. This task is becoming increasingly important with the development of new technology and services. Crucial area in this regard is the telemedicine and monitoring of the health status of a patient in home environment. Also hospital departments require increasingly clinical data integration, mainly for the purpose of clinical research. **This thesis has as the main aim the design of model, in accordance with the requirements of procedural and semantic interoperability in healthcare, in signals field linked events.** This model is linked to existing solutions in fields of nomenclatures and standards in health care**.** To the best of our knowledge, we do not know about existence of such model/architecture._Its main part is the multi-layer model that contains part of events (acts), part of signals and part of evaluation representing background knowledge.

The main aim of the thesis is proposal of an integrated data model, which allows description of all obtained data and analysis of data with minimal loss of semantic information. This approach should allow for a clearer linkage of technology (automatic) data processing and medical domains.

The thesis aims to develop description of the conditions and procedures that lead to the expansion of awareness and usability of collected data in a wider range. These procedures are demonstrated in two cases study from clinical and experimental part of medicine. Specific aims of this thesis are the following:

1. To propose an ontology model for heterogeneous data (clinical information and signal) with emphasis on the representation of the signal.

- The ontology model defines relationships of classes in context of real word where the representation is formed by relation *has* or *is*. The model defines how there are formally linked subjects and observations within the architecture.

2. To propose a multi-layer data model for heterogeneous data (clinical information and signal) with emphasis on the representation of the signal.

- Besides the ontological model we define function structure of data model into three layers which represent single level of processing data from row form to complex description of signal. The complex description of signal represents the middle-level of knowledge.

3. To define this model in specific clinical area, specifically in the obstetrics area.

- The first area of our efforts is clinical documentation. The reason for more complexity of record is given by ever-increasing demand for the possibility of processing data retrospectively. For such a process we need also raw data, such as origin signals.

4. To define this model in specific area of medical experiments, in particular electrophysiological and coronary experiments.

- The experimental area is very useful for evaluation of proposed model because allows to use whole design.

3. Working Methods, Thesis Structure

This chapter briefly introduced structure and content individual chapters. In Chapter 3 is stated the theoretical background from area of interoperability, standards and information technologies in medicine, design of systems and the state of the art in this area. The last two part of Chapter 3. present short description of UML and XML format. The Chapter 4 deals with storage, representation and analysis of heterogeneous data. This is important part for next work. Chapter 5 states the first case study in obstetrics area. Chapter 6 deals with extension of standards to next level of data and information – creation of multi-layer data model. This chapter contains main part of thesis. Chapter 7 contains the second case study for extension approach of data collection in medical experiments. Applications in this chapter are designed and implemented with accordance of multi-layer data model. Chapter 8 contains summary of our thesis, main contribution and achievements. Chapter 9 contains discussion and conclusion of this thesis.

4. Results

We have presented a proposed ontology and data model, which allow semantic description of a signal. This is the main achievement of the thesis. It is necessary to stress that the ontology and model can be used for any type of measured signal independent on its morphology, temporal and frequency characteristics and the signal (or its parts) can be linked to events occurring during the signal measurement. The signal can be structured by segmentation to parts and individual points, which allows its representation in symbolic form with direct link to events, which occurred during signal measurement. Symbolic representation allows to create a link between machine processing and knowledge of expert, because information is defined in context of both signal and related events and moreover it is readable and understandable both for a computer and a human.

We proposed a model (ontology) (see Figure 1), which is based on a case study describing the clinical setting – in gynecologic-obstetrics department – that defines representation and structure of clinical events. In this case we performed an analysis of obstetrics area and defined a domain model (ontology). We validated the model in the application of electronic labor book, which has been designed for practical application, and is deployed at the University Hospital, Brno. Our proposal focuses on the clinical part of the process and is designed mainly for the acquisition of medical information. In this case, the necessary information is the information about the newborn and his/her eventual hospitalization and treatment. Relationship of delivery and neonatology is important primarily due to the need to provide information for subsequent dispensary of the child,, especially if that is related to complications during labor.

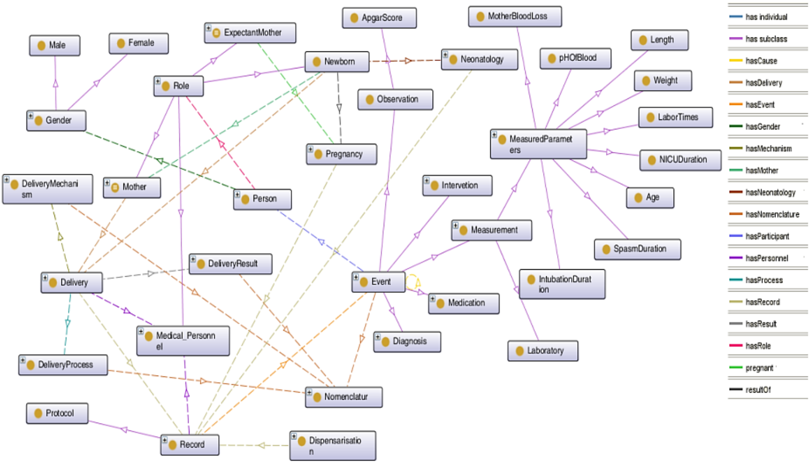

Figure 1 Ontology of Delivery

Further, we have defined an extended version of the model, which allows semantic description of a signal (type is not important) and its direct connection with clinical events.

Events are defined as observation, measurement or finding some facts about the focused subject. We can consider as an event, for example, statement of diagnosis, medication, intervention, measurement or observation. In the case of the measurement, the event may be measured signals and/or the results of laboratory test, which is carried out on the basis of samples. On the other hand the observation is based on subjective evaluation from a person (expert). An event can be connected with certain vocabulary (codebook, nomenclature, other ontology).

Signals are the foundation of modern medical diagnostics. With the discovery of ECG biomedical signal provides a basis of diagnostics. A set of invasive and noninvasive tests is very wide and number of signals that can be obtained during the examination can be large. The standards do not include form for decomposition of signal (in general) into semantic description.

In terms of standards for communication and information exchange the most common approach is to attach signals by reference. There are a number of formats for storing signals and a many of them have a complex form header (e.g. format MFER contains complete information about the type of signal, the sampling frequency, sensitivity and size of data block in header). This information is essential for subsequent processing, but it does not allow semantic transmission. The problem is the variability of signals and the fact that more complex description in the header means more complex parser for the information retrieval. The signal contains a number of characteristic points and intervals, which may be important for subsequent evaluation of the signal. The identification of these intervals is the goal of most analyses. However, these intervals do not have to be given only by the nature of the signal. These intervals are typically associated with the physiological processes of the body. Events that affect the subject are addition to the characteristic interval. Of course these two definitions of intervals of the signal may overlap. For example, beginning and end of ventricular fibrillation can be determined directly from the signal. However, it can also be defined by saving events of beginning and end of ventricular fibrillation in the independent system with precise time synchronization. Thus defined points and complexes can be then represented using a semantic interoperability tools. In the next section we describe the design process, which defines storage of the signal with all the information and the transformation that converts the signal into a structured form.

Signal description is transformation of information to knowledge. This transformation represent the intermediate layer of knowledge that in created based on data because the signal description is connected with rules evaluation. In other word, this middle layer is between expert knowledge and signal description for computer processing and the content are rules assigned to symbolic signal description. Our knowledge is not only in a one layer, but in two layers - diagnosis and description of measurement. The model (ontology) generalizes the structure by dividing into three parts (characteristic points, interval, and complex), which allow to reach the same results as a firmly defined structure. This construct also allows mutual interaction with clinical events and serves as a basis for feature representation. The given rules are formed for each signal type separately. Sets of rules are therefore dependent on whether the processed signal is electrocardiogram (ECG), intracardiac signal, continuous recording of blood pressure, electroencephalogram (EEG), etc. Rules should be hence categorized according to the usability and information should be maintained, in which signal domain rules can be used. The rules for the description of ECG and description of EEG will be different, not only in parameters, but also in the domain, in which the description is carried out (for ECG rather the time domain, for EEG rather the frequency domain). It is obvious that there should be defined a possibility of working with uncertainty as in the top layer (diagnosis) as well as in the bottom layer (description) of knowledge. Form of uncertainty is limited by our knowledge representation (in our case it is the uncertainty when working with rules, such as weights, measures, trust, and distrust).The ontology is shown in Figure 2 and class model is shown in Figure 3. Part that defines leads and signals is called Lead layer. Part of preprocessing, processing, analysis, and complexes of characteristic points is called Analyze layer. Part that contains conditions, rules and evaluation is called Evaluation layer. Block of events is called Event layer. Lead layer and Analyze layer are connected simply via leads definition and their preprocessing, which is already defined in the Analyze layer. Furthermore, type of signals in Lead layer is connected to conditions in Evaluation layer. Definition of leads is linked to the block Evaluation in Evaluation layer, which allows direct evaluation of the actual signal. The last link from Definition layer is to the Event layer. This relationship defines the ability to assign an event to the whole signal. Analyze layer is connected to the Evaluation layer over blocks Characteristic points and Complex definition. This relationship is fundamental to the evaluation of the signal. Complexes are also connected to Events as an extension of the event itself. Evaluation is further connected to the block of derived signals.

There has been performed mapping of our proposed ontology to the concept of HL7 aECG model [30] (Figure 4) and ECG ontology [31] (Figure 5), which has proved the possibility of using our proposed model to representation of specific type of data.

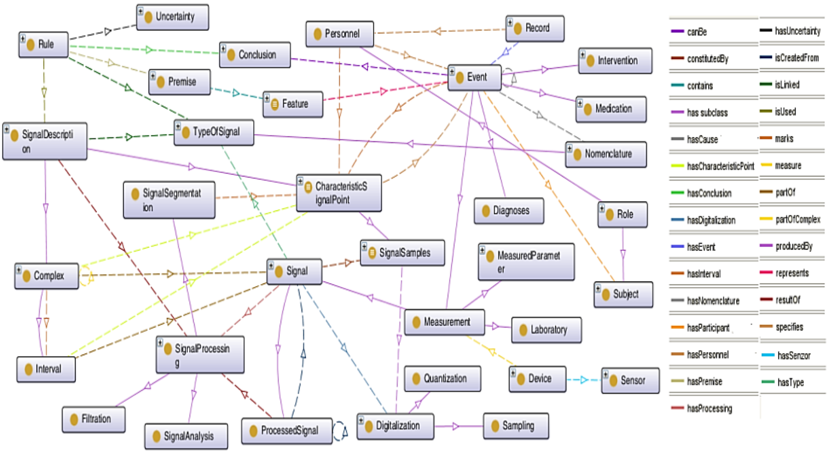

Figure 2 Ontology of Multi-layer model

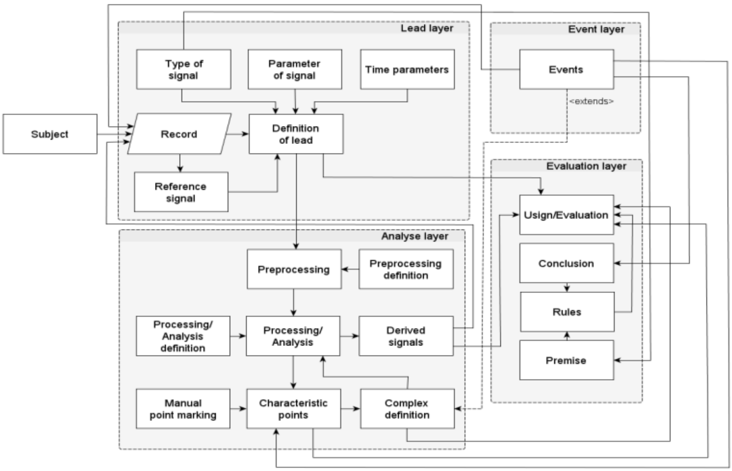

Figure 3 Class diagram of Multi-layer model

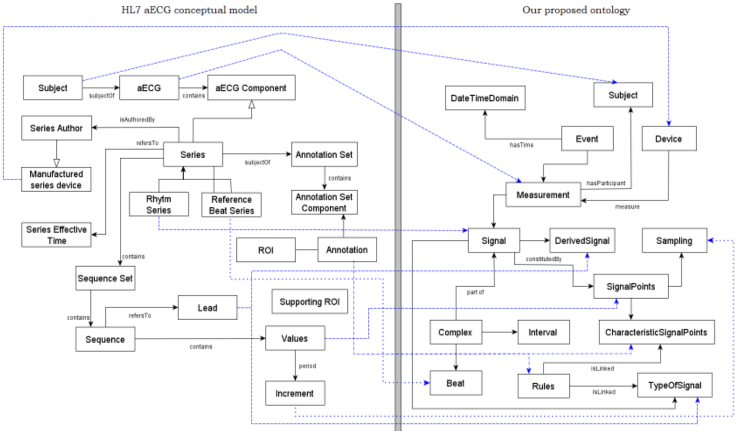

Figure 4 Mapping between the HL7 aECG conceptual model and our model

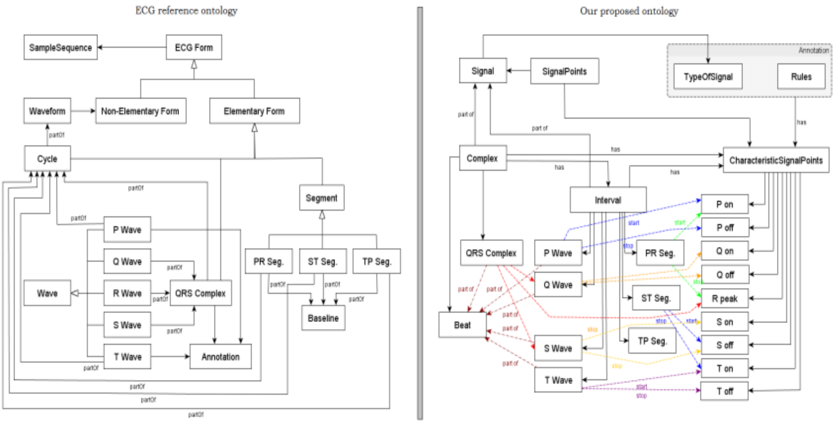

Figure 5 Model of the ECG on the side of the physition of ECG reference ontology and signal part of our proposed ontology

We have used the proposed model for representation of structure of participants, events, measured parameters and signals at a specific medical experiment in the area of extracorporeal circulation and electrophysiology. The experiment ontology is based on ontology of multilayer model. This case study has proved the importance of more general model of the signal and related events because these experiments generate large volumes of interrelated data and signals that have to be adequately represented for future evaluation of the experiments. Important subclass, which is added to the experimental ontology is Scenario. It is a subclass specific branches and phases of the experiment. The part of ontology with events of experiment is shown in Figure 6 and the part of ontology with signal is shown in.Figure 7

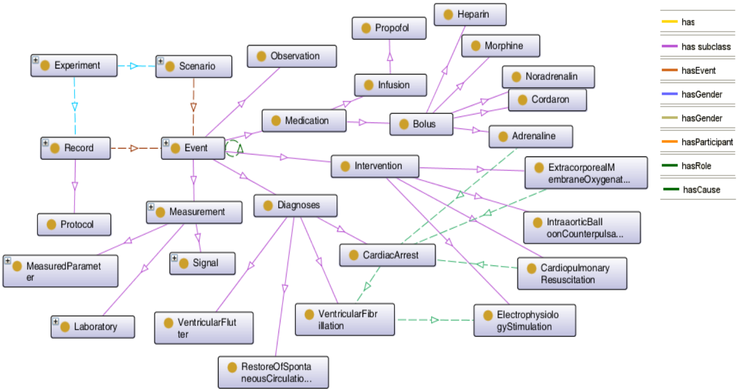

Figure 6 Example of events of experiment in the ontology

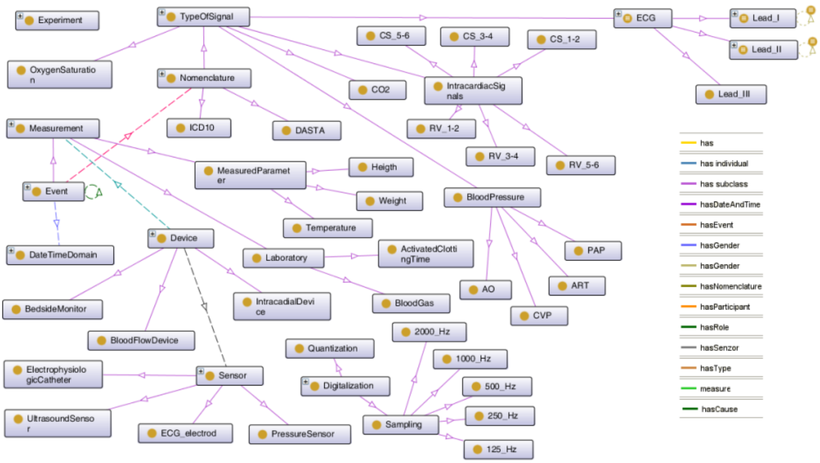

Figure 7 Example of signal part of experiment in ontology

We present an illustrative example of a simple inferring for the assignment of the characteristic points to parts of a signal and thus to define these parts as complexes and intervals with their mutual relations, where by assigning characteristic points to structures of signal defined complexes and intervals are assigned. The Figure 8 shows the relationship of signal characteristic points, complexes and intervals in the ontological graph.

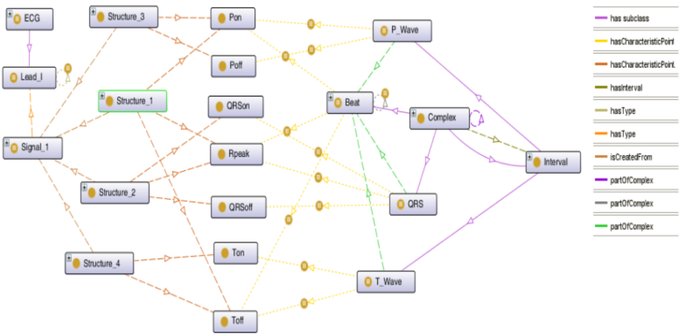

Figure 8 Ontology graph of relations among signal, its structures, charcteristic points and complexe and intervals

5. Discussion and Conclusion

The main aim of the thesis was to design an architecture, in accordance with the requirements of procedural and semantic interoperability in healthcare, in signal field linked events. This architecture is linked to existing solutions in the fields of nomenclatures and standards in health care. Its main part is the multi-layer model that contains part of events (acts), part of signals and part of evaluation that representing background knowledge. To achieve this aim, we divided it into several particulars aims in Chapter 2.

1. propose ontology model for heterogeneous data (clinical information and signal) with emphasis on the representation of the signal.

   The proposed ontology is formal representation of our model. We define the knowledge about single part of documentation with request to semantic interoperability. The main part of our work in ontology is design of relation between event and signal part and evaluation of the signal part (interval, complex). We compare our proposed ontology with HL7 aECG conceptual model and ECG reference ontology.

2. propose multi-layer data model for heterogeneous data containing common clinical data, events and signals together; design the signal part of model with support of semantic interoperability

   The core of the thesis is design of multi-layer model that is described in Chapter 6. We have specified the main distribution of data types and define the structure for their representing. Thus, we have obtained architecture, which allows defining general concept of signal leads with all necessary information, decomposition of this signal into important complexes using of defining of characteristic points and derivation of new signals. This signal domain is connected to the background knowledge, representing by compilation of signal type addicted rules. Our model defines two levels of knowledge which allow assessment of signal itself and also parts of the signal and overall evaluation of the state. And our model allows also linking to other information. Moreover, it is important to realize how documentation is valuable in the case that it is taken into consideration that data can be extracted also retrospectively. For such a procedure it is often necessary to have not only aggregated data but also the original data (signal).

3. in the obstetrics area specify the important part of domain model for description clinical process - main areas of clinical information – in our model

   We have developed a system in Obstetrics area that allows to record clinical data from labour. At this process we specify the important part of Obstetrics domain model, thereby we have tested model of basic areas of clinical information. For the classic description - in terms of electronic medical records - it is very important to define its content in structured form. In Chapter 5, we present led such a proposal, and then we ask led a question how to extend this record on the signals (see next paragraph). We examined the possibility of adding information from measured signals during delivery. We have arrived at the simple concept of adding the package classes that represent such information. It is clear that simply attaching the data signal with a reference is still more unsatisfactory, in terms of increasing requirements on stored data. It is necessary to define a model that allows representation of large quantities of data (which signals represent) in a clear description, relative to the context of the entire documentation.

4. define and develop this model in specific area of medical experiments

   We have defined and implemented the multi-layer model in The Experimental laboratory of Electrophysiology. Applications were implemented for recording of designed events, integrating of measured signals and parameters, their visualization, interfaces for processing and analyzing. Proposed model is at least as important for the medical experiment as for clinical practice, perhaps more. Experimental environment is the best opportunity for testing the model, because it supposes using the whole spectrum of measured and stored data. Therefore our conclusions are demonstrated on medical experiments.

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List of Candidate's Work Relating to the Doctoral Thesis

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- Bělohlávek, J. - Mlček, M. - Huptych, M. Svoboda T., Havránek Š., Ošťádal P., Bouček T., Kovárník T., Mlejnský F., Mrázek V., Bělohlávek M., Aschermann M., Linhart M. and Kittnar O.. Coronary versus carotid blood flow and coronary perfusion pressure in a pig model of prolonged cardiac arrest treated by different modes of venoarterial ECMO and intraaortic balloon counterpulsation. *Critical Care*. 2012, Volume 16, Issue 2, ISSN: 1364-8535. Available online on http://ccforum.com/content/16/2/R50. (IF: 4.61; 15 %)

- Spilka, J. - Chudáček, V. - Janků, P. - Koucký, M. - Lhotská, L. - Huptych, M. - et al. Using nonlinear features for fetal heart rate classification. *Biomedical Signal Processing and Control*. 2012, vol. 4, no. 7, p. 350-357. (IF:1.00; 5 %)

- Chudáček, V. - Spilka, J. - Janků, P. - Koucký, M. - Lhotská, L. - Huptych, M. Automatic evaluation of intrapartum fetal heart rate recordings. *A Comprehensive analysis of useful features:*

Physiological Measurement. 2011, Volume 32, Number 8, p. 1347-1360 (ÍF: 1.677; 5 %)

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Resume

With rapid development of IT and mobile technologies and their use in the medical field, it is necessary to guarantee the communication and representation of data in a much clearer form than ever before. Today, there are a number of standards that define syntactic form and structure of communication and representation as well as a number of classifications and dictionaries in a hierarchical arrangement, or even as an ontology, defining the content of a wide range of data communication and information exchange. In many aspects, these approaches allow semantic representation of data, however in the domain of signals and their integration with other data such representation is not yet resolved. In this thesis we present a proposed solution to representation of the signal on a higher level with the

definitions of signal integration with other data from the medical record. We have created an ontology and architecture of multi-layer data model that allows the definition of complex signal, with indication of characteristic (important) points and complexes and with link to clinical events and background knowledge base. The proposed model has been applied to and verified in clinical practice in obstetrics, and in medical experimental area.

Shrnutí

Se strmým rozvojem IT a mobilních technologií a jejich využívání v oblasti zdravotnictví, je zapotřebí zaručit komunikaci a reprezentaci dat v mnohem jasnější formě než kdy předtím. Dnes již sice existuje řada standardů, které definují jak syntaktickou formu a strukturu komunikace a reprezentace tak také řada číselníků a slovníků, v hierarchickém uspořádání nebo dokonce jako ontologie, pro definici celé řady údajů obsahu komunikace a výměny informací. V mnoha ohledech umožňují tyto přístupy plnou reprezentaci, avšak v oblasti signálů a jejich propojení s ostatními údaji tato reprezentace dořešena není. V této práci předkládáme návrh řešení pro reprezentaci signálu na vyšší úrovni s definicemi jejich propojení s ostatními údaji ze zdravotnického záznamu. Vytvořili jsme architekturu vícevrstvého datového modelu, který umožňuje komplexní definici signálu, s označením charakteristických a důležitých bodů a komplexů s propojením na bázi doménových znalostí a propojený s událostmi. Navržený model je prezentován v oblasti klinické praxe, v oblasti porodnictví, a v lékařské experimentální oblasti.